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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/640,366	08/13/2003	Michael D. DeGould	112559.00002	8438

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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/640,366	DEGOULD, MICHAEL D.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-14,16-20 and 25-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 12-14, 16-20 and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment filed July 17, 2007. All rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 112 – New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 12-14, 16-20 and 25-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A claimed temperature range is not sufficient specificity to be anticipatory. See Atofina v. Great Lakes Chem. Corp., 441 F.3d 991, 999, 78 USPQ 2d 1417, 1423 (Fed. Cir. 2006), where the court held that a reference temperature range of 100-500 degrees C did not describe the claimed range of 330-450 degrees C with sufficient specificity to be anticipatory. Further, while there was slight overlap between the reference's

preferred range (150-350 degrees C) and the claimed range, that overlap was not sufficient for anticipation.

The claims recite the limitation "to gel at 20-37 degrees Celsius". Although Applicant has given reason why the range is not new matter, there appears to be no disclosure of 37 degrees Celsius in the instant disclosure, the range recited is 20 to 45 Celsius. Furthermore none of the examples disclose the specific temperature of 37 degrees Celsius. Therefore the instantly recited range appears to be New Matter as supported by cited precedent and reasoning above.

Claim Rejections - 35 USC § 112 – Indefiniteness - Hybrid Claim

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A single claim which recites both a product and method steps of using that product is indefinite under 35 USC 112, second paragraph. See Ex parte Lyell, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990). Such claims should also be rejected under 35 USC 101 on the theory that the claim is directed to neither a "process" nor a "machine", but rather embraces or overlaps two different statutory categories of invention set forth under that statute, which is drafted so as to set forth the statutory classes of invention in the alternative only. Id. At 1551.

Instant claim 12 recites both a product (a syringe loaded with a wound dressing) and a process (inhibiting the occurrence of alveolar osteitis as reflected in the phrase "for inhibiting the occurrence of alveolar osteitis and pain following tooth extraction or

jaw cyst removal"). Claim 12 is thus rejected (along with its dependent claims) as follows on the theory that the claim is directed to neither a "process" nor a "product" exclusively.

Claim Rejections - 35 USC § 102 – Anticipation (Previous Rejection)

1) Claims 12-13 and 18 were rejected under 35 U.S.C. 102(b) as being anticipated by Berggren et al. (US 5,620,700). The rejection is maintained.

Applicant's Arguments

Applicant has amended to claims to add the limitation "to gel at 20 to 37 degrees Celsius". Applicant argues Berggren specifically states that the disclosed material cannot be a gel below 38 degrees Celsius. Applicant also implies the compositions cannot be gels at temperatures below 38.

Examiner's Response

The Examiner cannot find where the reference states the disclosed material cannot be a gel below 38 degrees Celsius. The compositions of the reference are flowable liquids at elevated temperatures and become more viscous at body temperature. This encompasses Applicant newly recited range. Therefore it would appear the fluid does gel within the recited range. In regards to the compositions not being gels, the reference also teaches the compositions are more viscous which still may be considered a "gel" just not necessarily a "flowable gel". The term gel encompasses different structures such as those encompassed by the definition: "**1:** a colloid in a more solid form than a sol; broadly**:** jelly 2; **2:** a thin colored transparent

sheet used over a stage light to color it; **3:** a gelatinous preparation used in styling hair" (Merriam-Webster Online Dictionary). Applicant does not supply a definition for the meaning of gel, therefore the interpretation of the instant claims is based on the dictionary definitions. Furthermore Applicant makes no recitation in the claims that the compositions have to be a flowable liquid at a certain temperature. Therefore this does not exclude the compositions of the reference. Claim 12 is also an improper a discussed above, therefore the process step recited in the claim carries no weigh in determining patentability.

Claim Rejections - 35 USC § 103 - Obviousness (Previous Rejections)

1) Claims 1-2, 4-6, 8-9,16, 19, 25-26 and 28-29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman (US 5,002,769) in view of Berggren et al. (US 5,620,700). The rejection is maintained.

Applicant's Arguments

Applicant asserts because Applicant argues both reference teach away from the instantly claimed invention. The implants by Friedman are dried to make non-gel implants for dental treatments. Friedman teaches away from any material that is flowable or is allowed to gel at body temperature or below. Berggren also teaches away because it discloses the compositions are flowable at temperatures above 38 degrees Celsius and are unlike gels or solutions or other fluids. Applicant further asserts, due to the amendments, the references no longer encompass all the limitation recited in the instant claims. This argument is not persuasive.

Examiner's Response

The combined references do not teach away from the instant claims insofar as the claims use transitional language "comprising" which leaves the claims open. Therefore additional steps such as drying the gels are encompassed by the instant claims. In regards to Friedman, the reference discloses the compositions gel and that an issue of concern was that the compositions did not gel "prematurely" not "at all" as implied by Applicant. The reference also discloses "the reaction mixture must gel for the film to dry as desired". The reactions also appear to occur at room temperature, therefore the compositions gel at 20-37 degrees Celsius as recited by the instant claims. As discussed above in regards to Berggren, there is no mention in the instant claims of at what temperature the gels had to be flowable. When the compositions reach body temperature 37 degrees Celsius, they become more viscous as stated above and may still be considered a gel. Therefore the references do not necessarily teach away from the instant claims, especially in view of the absence of a definition of the type of gel that is encompassed by the invention in Applicant instant specification.

2) Claim 7 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman (US 5,002,769) in view of Berggren et al. (US 5,620,700) as applied to claims 1-2, 4-6 and 8-9 in further view of Miller et al. (US 6,509,031). The rejection is maintained.

Applicant's Arguments

The combined reference no longer discloses all the limitations of the instant claims and therefore this is no longer a case of adding "known ingredients to known compositions". Applicant asserts the two references before Miller et al. is applied teach away from the instant invention. See arguments above in subsection 1.

Examiner's Response

See response above in subsection 1 in regards to Friedman and Berggren et al. The combined references do not teach away from the instant claims and therefore this is still a case of adding "known ingredients to known compositions".

3) Claims 3, 10, 14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman (US 5,002,769) in view of Berggren et al. (US 5,620,700) as applied to claims 1-2, 4-6, 8-9,16, 19, 25-26 and 28-29 in further view of Higashi et al. (US 4,906,670). The rejection is maintained.

Applicant's Arguments

The combined reference no longer discloses all the limitations of the instant claims and therefore this is no longer a case of adding "known ingredients to known compositions". Applicant asserts the two references before Miller et al. is applied teach away from the instant invention. See arguments above in subsection 1.

Examiner's Response

See response above in subsection 1 in regards to Friedman and Berggren et al. The combined references do not teach away from the instant claims and therefore this is still a case of adding "known ingredients to known compositions".

Claims 1-10, 12-14, 16-20 and 25-29 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612